

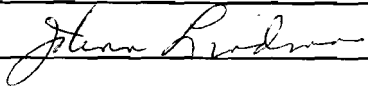
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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)									
I hereby certify that this correspondence is being electronically transmitted to the USPTO addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450		Application Number	Filed								
on <u>July 8, 2010</u>		10/616,622	July 10, 2003								
Signature <u></u>		First Named Inventor									
Typed or printed name <u>JoAnn Lindman</u>		Daniel M. Lafontaine									
		Art Unit	Examiner								
		3734	Yabut, Diane D.								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.</p> <p>I am the</p> <table border="0"><tr><td><input type="checkbox"/> applicant/inventor.</td><td><u>/glenn m. seager/</u></td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td><td>Signature <u>GLENN M. SEAGER</u> Typed or printed name</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>36,926</u></td><td><u>612.677.9050</u> Telephone number</td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td><u>July 8, 2010</u> Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<input type="checkbox"/> applicant/inventor.	<u>/glenn m. seager/</u>	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	Signature <u>GLENN M. SEAGER</u> Typed or printed name	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>36,926</u>	<u>612.677.9050</u> Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>July 8, 2010</u> Date
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<input type="checkbox"/> *Total of _____ forms are submitted.
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This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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## REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

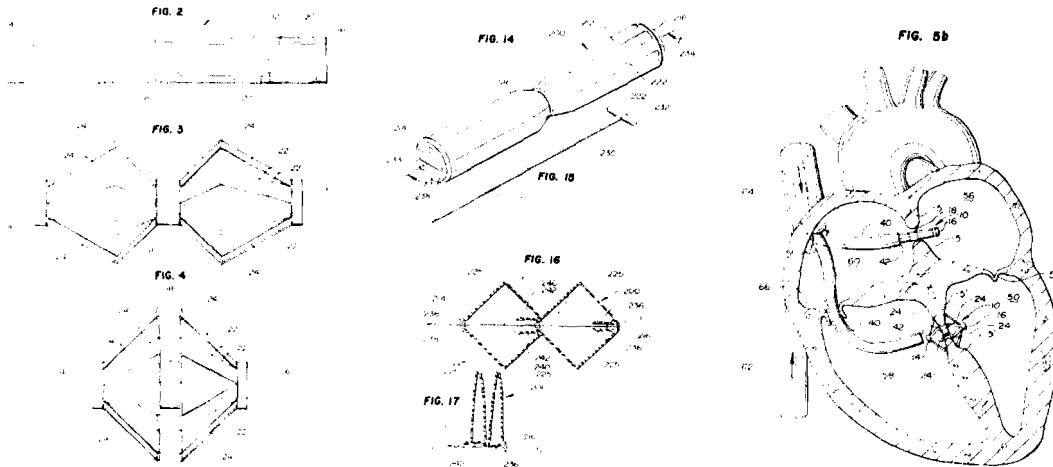
Appellants have carefully reviewed the Final Office Action of April 13, 2010 and the Advisory Action of June 17, 2010. Currently, claims 1-14, 16-29, and 31-41 are pending in the application. Claims 11, 12, and 14 have been withdrawn and claims 1-10, 13, 16-21, and 31-41 have been rejected by the Examiner. Appellants hereby request a pre-appeal conference and file this pre-appeal conference brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested.

Claims 1-10, 13, 17-21, 23-29, and 31-41 were rejected under 35 U.S.C. §103(a) as unpatentable over Huebsch et al. (U.S. Patent No. 6,312, 446), hereinafter Huebsch, in view of Hart (U.S. Patent No. 5,846,251) and Lafontaine et al. (U.S. Patent No. 5,964,782), hereinafter Lafontaine. Applicants respectfully traverse the rejection for at least the reasons that the references do not teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. As such, these claims are believed to be allowable over these references.

The rejections of independent claims 1, 26, and 33 rely largely upon an erroneous interpretation of the disclosure of Huebsch. As noted in the communication of June 3, 2010, Huebsch has attempted to rely upon descriptors for the various states of an apparatus for closing a septal defect which are somewhat at odds with the related descriptors employed in the pending application. The Examiner clearly errs by selectively applying the differing descriptive language of Huebsch. The Patent and Trademark Office (“PTO”) determines the scope of claims in patent applications not solely on the basis of the claim language, but in light of the specification as it would be interpreted by one of ordinary skill in the art.

Figs. 2, 14, and the upper device of Fig. 5b are depicted in the state in which the devices are delivered to the deployment site through catheter 40 of Huebsch. Fig. 2 is explicitly identified as a delivery state at col. 2, lines 57-58. The device has a generally cylindrical initial shape (with an optional waist in Fig. 14) which allows it to be advanced through the vasculature within catheter 40 and eventually through the septal defect to be repaired.

To facilitate the following discussion, illustrative figures from Huebsch are reproduced below:



Figures 3 and 16 illustrate intermediate states which the device may assume after delivery and during its mechanical transformation into a plug. (Col. 2, lines 59-62). Finally, Figs. 4, 17, and the lower device of Fig. 5b illustrate the devices after the mechanical transformation into a delivered plug. The Examiner has also made reference to Figs. 21 and 22 which appear to be identical to Figs. 16 and 17 respectively with the exception of the addition of four straight, as illustrated in the cited figures, protrusions 270, which are disposed two protrusions each to opposable struts 212 of a single pair of struts near hinge points 225 of device 200. Note that protrusions 270 are not present on the lower struts of Fig. 21. The straight protrusions 270 of Figs. 21 and 22 are described with no further comment as:

“The septal defect closure devices and apparatus disclosed herein may further comprise a plurality of tissue hooks located thereon to anchor the device in place in a septal defect. For example, FIGS. 21-22 show a sectional view of the device as in FIGS. 14, 16 and 17 further including a plurality of tissue hooks 270.” (Col. 7, lines 32-37.)

At page 4 of the Final Office Action, the Examiner initially makes reference to “the delivery member which includes a collapsible backing or support **200** with proximal facing tissue engaging hooks **270**”. It is believed that the Examiner may have been attempting to suggest that a collapsible backing may be associated with closure device 200, comprising struts 212, and that device 200 is delivered through an elongate delivery member 40. There is no “backing or support” covering the cited devices; however Hubsch does suggest that the struts comprising the device “may be covered or coated with a fabric and/or elastic material”. In particular, there is no “plurality of fibrous tissue engaging members disposed on the backing” of Hubsch and no backing appears to be disclosed as present or desirable in the only embodiment

in which hooks 270 are affixed to struts 212. Were such backing to be present, it would easily be seen, either covering the struts or festooned between the struts, in Figs 21 and 22 in which details as fine as the individual hooks are visible.

Although the Examiner makes reference to a “backing or support” the term “backing” does not appear in Huebsch. The term “support” is used only to refer to support struts 212. Although the Examiner is not bound by the specific word choices employed by Huebsch, “USPTO personnel must always remember to use the perspective of one of ordinary skill in the art.” (MPEP 2106) The Examiner’s assertion in the Advisory Action that ‘a “backing” may considered to be “aid or support of any kind” ... and that the device 200 forms the backing of a septal defect and therefore reads on this limitation” is clearly an erroneous selection of definitions which is at odds with the specification as it would be interpreted by one of skill in the art. “Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.”

The Examiner then asserts, still at page 4 of the Final Office Action that the device (200) of Huebsch has a “non-collapsed, non-deployed position” which is characterized as “being generally conically shaped and having a center portion 216 distally spaced from the periphery”. Center portion 216 is in direct contact with and surrounded by the distal ends, the periphery defined by struts 212, in the non-deployed delivery position and so is not distally spaced therefrom. Although no state of the device 200 of Huebsch, viewed as a whole, would be described as conical, the Examiner’s characterization apparently is intended to apply to no more than one quarter of the intermediate state of Figs. 3 and 16 and accordingly does not correspond to either the conical “non-collapsed delivery position” or the disc-like “collapsed deployed position” recited in the claims. The device 200 of Huebsch transforms from a cylinder to a bipyramid on transforming from the non-deployed position to the deployed position (Fig. 5b).

The device 200 of Huebsch moves between the initially (radially collapsed / longitudinally non-collapsed) cylindrical delivery state to a (radially expanded / longitudinally collapsed) state comprising either two or four conical portions depending on the embodiment, such that the proximal and distal struts may press against opposed surfaces of the septal defect. As also seen in the cited figures above, there is no backing having a plurality of fibrous tissue engaging members thereon, the fibrous tissue engaging members entangling the backing when

the backing is in the collapsed (generally disc shape) position. The hooks 270 are attached to struts 212 and engage only the tissue to be repaired.

As recited in pending claim 1 as well as, *mutatis mutandis*, in claims 26 and 33:

“the closure component including a collapsible backing movable between a non-collapsed delivery position, in which the backing has a generally conical shape with a center portion of the backing distally spaced from a periphery of the backing, and a collapsed deployed position, in which the backing center portion is collapsed proximally toward the backing periphery to have a generally disc shape, and a plurality of fibrous tissue engaging members disposed on the backing and oriented in a non-engaging orientation when traveling in a distal direction and in an engaging orientation when traveling in a proximal direction, the fibrous tissue engaging members entangling the backing when the backing is in the collapsed position”

Two primary issues must be addressed. As noted above, the state of the device 200 of Huebsch during delivery is cylindrical and not conical and in the deployed state is a bipyramid or a double bipyramid. Further, the four hooks 270 of Figs. 21 and 21 extend essentially perpendicular to the surfaces of struts 212 and thus are oriented in tissue engaging configurations as they pass through the septal defect in the distal direction which is contrary to the orientation recited in the pending claims. At least the distal pair of hooks extending from near the midpoint of the distal strut in Fig. 5b would be expected to engage the septal opening as the device passes through following ejection from catheter 40 at a point proximal of the septal opening.

As seen in Figs 3-5, the non-collapsed conical delivery state and collapsed deployed disc states of the pending specification and claims refer to the longitudinal collapse of an initially extended conical configuration to a flattened disc of substantially the same radial extent and would be so understood by one of ordinary skill in the art in view of the specification and drawings. The corresponding states disclosed by Huebsch refer to simultaneous proximal and distal longitudinal collapse from a generally cylindrical non-deployed delivery state to a deployed state comprising either a bipyramid or two bipyramids with a common apex.

Although the Examiner has characterized the discussion of the references as an attack on the individual references, it is the Appellant’s position that it was necessary to discuss the disclosure of the references individually to demonstrate that they do not disclose the features attributed to them by the Examiner. Absent a disclosure of the features asserted to be provided

by the disclosure of a reference, its combination with others references cannot render the combination obvious.

The Examiner acknowledges that Huebsch does not disclose the collapse actuator. As discussed in the communication of June 3, 2010, the actuator of Hart is not a “collapse actuator” of the pending claims, but rather an expansion actuator. The Examiner errs by equating mere deformation of distal end 301 of Hart with collapse. Instead, both element 301 and element 43 assume expanded profiles as a result of the withdrawal of the actuator as shown in Figs. 28E-28H.

In discussing Lafontaine, the Examiner notes that the hooks of the claims are not explicitly located upon the exterior surface of the conical collapsible backing; however Appellant notes that the plurality of fibrous tissue engaging members are recited as oriented in a tissue engaging orientation when traveling in a proximal direction. As seen in Figs. 3-5, it is only those tissue engaging members which are on the outside of the conical backing which are so oriented. It is those same tissue engaging members which entangle the backing when the backing is in the collapsed position of Fig. 5. This is not a limitation read into the claim from the specification, but rather a structural feature which results from the respective positions of the tissue and the hooks relative to the backing and would be so understood by one of ordinary skill in the art.

For these reasons and others discussed in greater detail earlier, Huebsch does not disclose the required structural states for delivery and deployment; the expanding actuator of Hart does not overcome the deficiencies of Huebsch; and the interior hooks of Lafontaine do not overcome the deficiencies of Huebsch in view of Hart. All of the pending claims are allowable over the cited prior art. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: July 8, 2010

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